

## **REMARKS**

In response to the above-identified Office Action (“Action”), Applicants traverse the Patent Office’s rejection of the claims and seek reconsideration thereof. Claims 1-137 are pending in the present application. Claims 29-114, 123-126, 129-131 and 134-137 remain withdrawn. Claims 1-28, 115-122, 127, 128, 132 and 133 are rejected. In this response, no claims are amended, no claims are cancelled and no claims are added.

### **I. Claim Rejections – 35 U.S.C. §102**

In the Action, claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,667 issued to Ham et al. (“Ham”). Applicants respectfully traverse the rejection.

It is axiomatic to a finding of anticipation that each and every element of the rejected claim be found within a single prior art reference.

For the reasons discussed in the previous Response to Office Action dated February 2, 2009 and those herein, Ham fails to teach at least the elements of “a catheter shaft having a catheter proximal section and a catheter distal section...a tendon disposed within a first lumen of said catheter shaft said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section...said tendon being able to deflect said catheter distal section when being pulled on” as recited in claim 1.

Ham describes a catheter with an expandable region 12 formed of a tubular material that continues to the distal end of the catheter. See Ham, Abstract. Specifically, Ham discloses a catheter having “an expandable region 12 beginning at the distal end of the catheter body and continuing the catheter body in a one-piece configuration.” See Ham, col. 5, lines 12-15. The distal portion is defined by Ham as extending from side port 21 in sidewall 22 of tubular catheter body 11 to port 23. See Ham, col. 5, lines 23-25.

The Patent Office alleges that “Ham discloses...a catheter shaft (internal compartment 26 or 11) with a proximal section (bottom) and distal (top), a tendon (13) disposed within a first lumen (internal area of 17) which is approximately centrally located a the proximal section (note lumen position is central as it approaches near 44) and at the distal end the lumen is off center (note lumen position is off center as it approaches near top area and numeral 17)...” and “...deflection of the distal end by the tendon (compare figure 1 to 1a).” See Action, pages 2-3.

As an initial matter, as discussed in the previous Response, Applicants disagree with the Patent Office’s characterization of proximal and distal sections between areas 44 and 17 of the catheter in Ham for at least the reasons that such a characterization is not consistent with what is stated in Ham. See Ham, col. 5, lines 23-25. Thus, the Patent Office has not shown where within Ham the elements of “said catheter shaft said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section” are disclosed.

Applicants further submit that the Patent Office has not pointed to a portion of Ham teaching a “tendon being able to deflect said catheter distal section when being pulled on.” In particular, the Patent Office alleges that internal compartment 26 or 11 of Ham teaches the claimed catheter shaft having a catheter proximal section and a catheter distal section. The Patent Office then alleges that deflection of the catheter distal section is shown by comparing Figures 1 and 1a of Ham. As can be seen from the figures in Ham, however, the alleged catheter shaft 26, 11 extends only to the region labeled as 14. Upon comparing Figure 1 to Figure 1a as suggested by the Patent Office, Applicants are unable to see where any sort of deflection of the catheter shaft distal section when the alleged tendon 13 is pulled is shown. Applicants recognize that an axial spacing between ends 14 and 15 of expandable region 12 changes when tendon 13 is pulled, but the region between ends 14 and 15 is not part of “the catheter shaft...having a catheter distal section” and even if it were, *it does not deflect* when tendon 13 is pulled on.

Accordingly, Applicants respectfully request that if the Patent Office chooses to maintain the rejection on this basis, that the Patent Office specifically identify which portion of the catheter in Ham the Patent Office believes is deflected when tendon 13 is pulled. Applicants do not believe the Patent Office’s statement “compare figure 1 to 1a” sufficiently establishes where

within the reference the element of “a catheter shaft having...a catheter distal section...said tendon being able to deflect said catheter distal section when being pulled on” as claimed.

Since, for at least the foregoing reasons, Ham fails to teach each and every element of claim 1, claim 1 is not anticipated by the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §102 over Ham.

## **II. Claim Rejections – 35 U.S.C. §103**

A. In the outstanding Action, claims 2-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,123,699 issued to Webster, Jr. (“Webster”) in view of Ham. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, the Patent Office must set forth “some articulated reasoning with some rational underpinning to support the conclusion of obviousness.” See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). In combining prior art elements to render the claimed combination of elements obvious, the Patent Office must show that the results would have been predictable to one of ordinary skill in the art. See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, Section III(D), issued by the U.S. Patent and Trademark Office on October 10, 2007.

Webster describes a steerable catheter. As admitted in the Action, Webster fails to disclose “said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section” as recited in part in claim 1.

Claims 2-21 depend from claim 1 and incorporate the limitations thereof. Applicants respectfully submit that for at least the reasons previously discussed with respect to the rejection under 35 U.S.C. §102 and in the above paragraph, the proposed combination of Webster and Ham does not teach or suggest all of the claim limitations of claims 2-21. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2-21 under 35 U.S.C. §103 in view of Webster and Ham.

**B.** In the outstanding Action, claims 22-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Webster in view of Ham in further view of U.S. Patent No. 6,254,598 issued to Edwards et al. (“Edwards”). Applicants respectfully traverse the rejection.

Claims 22-28 depend from claim 1 and incorporate the limitations thereof. Applicants respectfully submit that for at least the reasons previously discussed, the proposed combination of Webster, Ham and Edwards does not disclose or render predictable each of the elements of claims 22-28. In particular, Edwards does not cure the deficiencies of Webster and Ham with respect to the elements of “...a tendon disposed within a first lumen of said catheter shaft said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section...said tendon being able to deflect said catheter distal section when being pulled on.” Applicants respectfully request reconsideration and withdrawal of the rejection of claims 22-28 under 35 U.S.C. §103 in view of Webster, Ham and Edwards.

**C.** In the outstanding Action, claims 115-122, 127-128, 132 and 133 are rejected under 35 U.S.C. §103(a) as being unpatentable over Webster in view of Ham in further view of Edwards and in further view of U.S. Patent No. 6,770,070 issued to Balbierz (“Balbierz”). Applicants respectfully traverse the rejection.

Claims 115-122, 127-128, 132 and 133 depend from claim 1 and incorporate the limitations thereof. Applicants respectfully submit that for at least the reasons previously discussed, the proposed combination of Webster, Ham, Edwards, and Balbierz does not disclose or render predictable each of the elements of claims 115-122, 127-128, 132 and 133. In particular, Balbierz does not cure the deficiencies of Webster, Ham and Edwards with respect to the elements of “...a tendon disposed within a first lumen of said catheter shaft said first lumen being approximately centrally located within said catheter shaft at said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section...said tendon being able to deflect said catheter distal section when being pulled on.” Applicants respectfully request reconsideration and withdrawal of the rejection of claims 115-122, 127-128, 132 and 133 under 35 U.S.C. §103 in view of Webster, Ham, Edwards, and Balbierz.

### CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 1-137, are now in condition for allowance and such action is earnestly solicited at the earliest possible date. If there are any additional fees due in connection with the filing of this response, please charge those fees to our Deposit Account No. 02-2666. Questions regarding this matter should be directed to the undersigned at (310) 207-3800.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN LLP

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By: Stacie Sundquist  
Stacie J. Sundquist, Reg. No. 53,654

1279 Oakmead Parkway  
Sunnyvale, CA 94085-4040  
Telephone (310) 207-3800  
Facsimile (408) 720-8383

### **CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted electronically via EFS Web to the United States Patent and Trademark Office on June 12, 2009.

Si Vuong  
Si Vuong